REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Upon entry of this Amendment, claims 1, 3, 5-11, and 13-18 will be pending in the present application. Claims 13-18 have been rejoined. Claims 9, 10, 15, and 17 are deemed allowable by the Examiner if rewritten in independent form. The Applicant is grateful for the Examiner's notice that claims 9, 10, 15, and 17 are allowable. Claims 9, 10, 15, and 17 have been rewritten in independent form. In addition, the applicant appreciates the Examiner's decision to rejoin claims 13-18.

Claims 1, 3, 5, and 6 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. U.S. 6,192,876 to Denyer et al. ("the '876 patent"). Claims 1, 6-8, and 12 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. U.S. 6,584,971 to Denyer et al. ("the '971 patent").

Applicant appreciates the Examiner's notice that this rejection could be overcome by filing the appropriate showing under 37 C.F.R. § 1.132 that the invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another," or by an appropriate showing under 37 C.F.R. § 1.131. However, Applicant respectfully traverses this rejection for the reasons presented below.

In respiratory drug delivery, medication is aerosolized and then inhaled by the user into their lungs. Many drugs may require a larger dose than can be inhaled in a single breath. Therefore, in order to obtain the prescribed dose or treatment. The patient must inhale the aerosolized drug over multiple inhalations until the desired dose has been achieved. The patient can then discontinue drug delivery until the next dose is due. The prior art, as exemplified by the '876 and the '971 patents, discloses devices that calculate the dose over multiple inhalations. The '876 patent discloses a device that calculates the dose of medication delivered based upon the time-dependent concentration of the medication in the chamber (col. 16, lines 12-25). Similarly, the '971 patent is principally concerned with maximizing the amount

of drug delivered to the lungs. It is known that a portion of each inhalation fills the upper airway, or deadspace, and is lost during exhalation. In devices that continuously atomize, a substantial portion of the medication is wasted. One known solution to resolve this problem is pulsed atomization that would deliver medication during the first 50% of the inhalation cycle. As such, medication delivery would be shut off during the subsequent 50% of the inhalation cycle. This medication-free air, chase air, fills the upper airway rather than medication-laden air. Although such a method is effective, the design could be further improved upon. The '971 patent discloses a device that utilizes the deadspace of the user to calculate the maximum amount of medication that can be delivered into the lungs. Often this system will permit drug delivery for a period longer than 50% of the inhalation cycle. As such the total number of breaths required to deliver a full dose may be reduced thus speeding drug delivery.

Rather than being directed to calculating when a dose has been delivered in a pulsed delivery system (the '971 patent) or in a system in which the concentration of drug changes over time (the '876 patent), the present invention is directed to collecting breath information over a number of treatments or doses rather than a single dose. The unique features of these references could be utilized in conjunction with the present invention. In fact, the concept of pulsed drug delivery is shown in FIGS. 6 and 7 and described at page 16, lines 30-34 in the present application. As recited in independent claim 1, the present invention has a data carrier which stores breath information that spans a number of treatments or doses. In addition, the present invention has a data analyzer that derives characteristics of the patient's breathing, a trend generator for analyzing the breath information of the patient's breathing over a number of treatments. Similarly, independent claims 5 and 6 recite that the present invention analyzes breath information over a number of treatments. The breath information of the present invention spans multiple doses or treatments. This unique feature of the present invention allows physicians the ability to obtain compliance data over multiple treatments or doses. The references presented by the Examiner simply do not disclose this unique. Accordingly, reconsideration of the Examiner's rejection to claims 1, 5, and 6, as well as all claims dependent thereon, is requested.

This response is being filed with a request under the provisions under 37 C.F.R. § 1.136(a) to extend the period for response by three months. The original due date was April 3, 2006. Therefore, the period for response is extended to July 3, 2006. The Commissioner is authorized to charge the three-month extension fee, as well as any other fee required under 37 C.F.R. §§ 1.16 or 1.17, to deposit account no. 50-0558.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to this effect is earnestly solicited.

Respectfully submitted,

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